

specification on page 15, lines 13-23. Such uniform constructs are not contemplated by Schlameus, who instead discloses a suspension of microcapsules in agarose surrounded by an agarose donut (column 12, lines 35-45). Applicant submits that new claims 44-52 are patentable in view of Schlameus.

Applicant also submits that claims 44-52 are patentable over Schlameus in view of U.S. Patent No. 5,266,326 to Barry, *et al.* (Barry); PCT Publication No. WO92/19195 by Dionne, *et al.* (Dionne); and U.S. Patent No. 5,354,736 to Bhatnagar (Bhatnagar). Barry discloses a degradable hydrogel matrix designed to eventually "revert to the gel or solution state" (column 3, line 65) and be resorbed by the body. Dionne discloses an implantation vehicle containing cells in a hydrogel matrix core surrounded by a membrane that may be formed from the same hydrogel. Bhatnagar teaches use of a hydrogel having peptides attached. None of these references disclose or suggest a hardened hydrogel construct in which dissociated cells are uniformly distributed as recited in claim 44. Barry teaches away from the invention by disclosing an implant that is designed to be resorbed without being replaced by endogenous tissue (column 3, lines 64-66); indeed, Barry's implant is meant to prevent the formation of tissue, and the combination of his matrix with cells would thwart this purpose. The core of the matrix disclosed by Dionne need not be hardened before implantation (page 18, lines 18-22); however, the hardened exterior is cell-free (page 16, lines 18-20). In contrast, claim 44 recites that the cells are uniformly distributed throughout the hydrogel. Bhatnagar does not teach use of a hydrogel without peptides. Applicant submits that Barry teaches away from combination with Schlameus and that the combination of Dionne and/or Bhatnagar with Schlameus neither results in the present invention nor renders it obvious. Applicant submits that claims 44-52 are patentable over Schlameus, Dionne, Barry, and Bhatnagar, either separately or in combination.

Applicant also submits that new claims 44-52 are patentable over Schlameus in view of U.S. Patent No. 4,632,120 to Nevo, *et al.* (Nevo); U.S. Patent No. 5,041,138 to Vacanti, *et al.* (Vacanti A); and Vacanti, *et al.*, "Selective Cells Transplantation Using Bioabsorbable Artificial Polymers as Matrices," *Journal of Pediatric Surgery*, 23: 3-9 (1988) (Vacanti B). Applicant submits that Nevo neither discloses nor renders obvious forming an implant comprising a hydrogel, wherein hardening of the hydrogel is completed post-implantation. Rather, the implant of Nevo is hardened prior to implantation (column 3, lines 48-50). In addition, the implants of

Vacanti A and Vacanti B require formation of fibers (column 4, lines 56-59; Vacanti B (p.7, column 2, "branching fiber networks . . . satisfy these needs") or a mesh (column 6, lines 47-50) to which the cells must be attached (column 10, lines 11-13). No such mesh or fibers are required to perform the instant invention. Vacanti B further teaches away from the invention by disclosing a solid polymer disk on which cells are seeded in a monolayer (p.7, column 2, "Polymer discs seeded with a monolayer of cells . . ."). Applicant submits that the combination of Schlameus with one or more of Nevo, Vacanti A, and Vacanti B does not result in the claimed invention. Applicant submits that claims 44-52 are patentable in view of these references, taken either separately or in combination.

In light of the foregoing Amendment and Remarks, Applicant respectfully submits that the present case is in condition for allowance. A Notice to that effect is respectfully requested.

Please charge the \$296 fee under 37 CFR 1.16(c) for the new claims, any other fees associated with this filing, or apply any credits, to our Deposit Account No. 03-1721.

Respectfully submitted,



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